

902 KAR 11:030. Personnel standards.

RELATES TO: KRS Chapter 333

STATUTORY AUTHORITY: KRS 194.050

NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 authorizes the Cabinet for Human Resources to license and regulate medical laboratories in Kentucky, including the setting of qualifications for medical laboratory personnel. This administrative regulation establishes personnel standards for medical laboratory directors, supervisors, technologists, and technicians.

Section 1. Medical Laboratory Director. (1) A medical laboratory director shall, in addition to the responsibilities specified in KRS Chapter 333, be responsible for the following:

- (a) Technical and scientific operation of the laboratory;
- (b) Performance of tests made in the laboratory;
- (c) Reporting of findings of laboratory tests; and
- (d) Employment of qualified laboratory personnel and their in-service training.

(2) The director may serve the laboratory on a full-time or regular part-time basis.

(a) A director may not serve more than three (3) medical laboratories on a regular part-time basis, unless the director provides for an associate, qualified according to the standards in subsection (4) of this section, in each additional laboratory to serve as assistant director in each laboratory.

(b) An assistant director shall not serve more than three (3) laboratories.

(3) Commensurate with the laboratory workload, the director shall spend adequate time in the laboratory to effectively direct and supervise its technical operation. The director shall be available for personal or telephone consultation. If the director is to be continuously absent from the laboratory for more than one (1) month, the director shall make arrangements for a qualified substitute director.

(4) To qualify as a medical laboratory director, a person shall meet one (1) of the following requirements:

(a) Is a physician certified in anatomical or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possessing qualifications equivalent to those required for the certification.

(b) Is a physician certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one (1) of the laboratory specialties.

(c) Is a physician certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or any other national accrediting board in one (1) of the laboratory specialties.

(d) Is a physician certified by the American Society of Cytology to practice cytopathology or possessing qualifications which are equivalent to those required for certification.

(e) Is a physician who, subsequent to graduation, has two (2) years of experience in a medical laboratory approved by the cabinet.

(f) Holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject; and

1. Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or any other national accrediting board acceptable to the cabinet in one (1) of the laboratory specialties; or

2. Subsequent to graduation has two (2) years' full-time experience in one (1) of the laboratory specialties.

(5) A dentist certified by the American Board of Oral Pathology or possessing qualifications equivalent to those required for certification may serve as director of a medical laboratory specializing in the area of oral pathology only.

(6) An individual responsible for the direction of a medical laboratory for twelve (12) months be-

tween January 1, 1968, and May 4, 1977, may continue to serve as a medical laboratory director if one (1) of the following requirements is met:

(a) Holds a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and, subsequent to graduation, has four (4) years of pertinent full-time laboratory experience.

(b) Holds a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject, and subsequent to graduation, has six (6) years of pertinent full-time medical laboratory experience.

(c) Has achieved a satisfactory grade through an examination approved by the cabinet.

Section 2. Medical Laboratory Supervisors. (1) Each medical laboratory shall have a general supervisor and a technical supervisor. A general supervisor may be a technical supervisor in those specialties in which requirements of competency are met as provided in 902 KAR Chapter 11.

(2) The general supervisor shall be present on the laboratory premises during all hours in which tests are being performed.

(3) The technical supervisor shall spend adequate time in the laboratory to supervise the technical performance of the staff in the specialty and shall be available for personal or telephone consultation.

(4) Emergency procedures implemented outside regularly scheduled hours of duty may proceed without the general supervisor being on the premises if the technologist performing the tests is qualified to do so. The supervisor who is responsible for the result of the work shall review the tests during the next duty period, and a record shall be maintained reflecting the actual review.

(5) To qualify as a general supervisor, a person shall meet one (1) of the following requirements:

(a) Is a physician, or has earned a doctoral degree from an accredited institution with a major in one (1) of the chemical, physical, or biological sciences and, subsequent to graduation, has two (2) years of experience in one (1) of the laboratory specialties in a medical laboratory approved by the cabinet.

(b) Holds a master's degree from an accredited institution with a major in one (1) of the chemical, physical, or biological sciences and, subsequent to graduation, has three (3) years of pertinent full-time laboratory experience of which two (2) years have been spent working in the designated laboratory specialty in a medical laboratory approved by the cabinet.

(c) Is qualified as a medical laboratory technologist pursuant to Section 3 of this administrative regulation and, subsequent to the date of qualifying as a medical laboratory technologist, has four (4) years of pertinent full-time laboratory experience of which two (2) years have been spent working on the designated laboratory specialty in a medical laboratory approved by the cabinet.

(6) To qualify as a technical supervisor, the person shall meet competency requirements provided in 902 KAR Chapter 11.

(7) To serve as general supervisor of medical laboratory personnel specializing in the area of diagnostic cytology, a person shall qualify as a cytotechnologist pursuant to Section 3 of this administrative regulation and, subsequent to the qualification, have four (4) years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding ten (10) years.

(8) A person not meeting the training and experience requirements of subsection (5)(a),(b), and (c) of this section may qualify as a medical laboratory general supervisor if the person:

(a) Was performing the duties of a medical laboratory general supervisor anytime between January 1, 1968, and May 4, 1977; and

(b) Has fifteen (15) years of pertinent full-time medical laboratory experience. A minimum of thirty (30) semester hours of credit from an approved school of medical technology or toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major sub-

ject shall be considered equivalent to two (2) years of experience. Additional education shall be equated to the rate of fifteen (15) hours of credit for one (1) year of experience.

(9) An individual serving as a medical laboratory supervisor in Kentucky for a period of one (1) year prior to May 4, 1977, may continue to supervise the laboratory unless otherwise exempted in subsections (5), (6), (7), and (8) of this section. The cabinet may require, in the interest of the health, safety, and welfare of the people of this state and as a condition to issuance of an original or renewal license, the individual to satisfactorily demonstrate the ability to perform medical laboratory examinations and supervise a medical laboratory.

Section 3. Medical Laboratory Technologists and Cytotechnologists. (1) Medical laboratory technologists and cytotechnologists shall be in sufficient number to adequately supervise the work of technicians or trainees.

(2) An individual qualifying as a medical laboratory technologist shall:

(a) Perform tests requiring the exercise of independent judgment and responsibility with minimal supervision by the director or supervisors only in those specialties or subspecialties in which the technologists are qualified by education, training, and experience.

(b) Perform tests only under the direct supervision of the laboratory supervisor or qualified technologist in those specialties in which the medical laboratory technologist is not qualified by education, training, or experience.

(3) To qualify as a medical laboratory technologist, a person shall meet one (1) of the following requirements:

(a) Earn a bachelor's degree in medical technology from an accredited university or college.

(b) Successfully complete three (3) years of academic study (a minimum of ninety (90) semester hours or equivalent) in an accredited college or university which meet the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the cabinet and successfully complete completed a course of training of twelve (12) months in a school of medical technology.

(c) Earn a bachelor's degree in one (1) of the chemical, physical, or biological sciences, with an additional one (1) year of pertinent full-time laboratory experience or training in the specialty or subspecialty in which the individual performs.

(d) Successfully complete three (3) years (a minimum of ninety (90) semester hours or equivalent) in an accredited college or university with the following distribution of courses:

1. For those whose training was completed prior to September 15, 1963, the course work shall include twenty-four (24) semester hours in chemistry and biology courses of which six (6) semester hours are in inorganic chemistry, and three (3) semester hours are in other chemistry courses, and twelve (12) semester hours are in biology courses pertinent to the medical sciences; or

2. For those whose training was completed after September 14, 1963, the course work shall include sixteen (16) semester hours in chemistry courses which include six (6) semester hours in inorganic chemistry acceptable toward a major in chemistry, sixteen (16) semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in biology, and three (3) semester hours of mathematics; and

3. Has experience or training covering several fields of medical laboratory work of one (1) year and of a quality to provide education and training in medical technology equivalent to that described in paragraphs (a) and (b) of this subsection.

(e) A person not meeting the training and experience requirements defined in paragraphs (a), (b), (c), or (d) of this subsection may qualify as a medical laboratory technologist if the person:

1. Was performing the duties of a medical laboratory technologist any time between January 1, 1968, and May 4, 1977; and

2. Had ten (10) years of pertinent medical laboratory experience prior to May 4, 1977. A minimum

of thirty (30) semester hours of credit from an approved school of medical technology or toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject shall be considered equivalent to two (2) years of experience. Additional education shall be equated to the rate of fifteen (15) hours of credit for one (1) year of experience.

(f) Has achieved a satisfactory grade in a proficiency examination approved by the cabinet. After December 31, 1978, initial qualification as a technologist shall be in accordance with the requirements of paragraphs (a), (b), (c), or (d) of this subsection.

(4) To qualify as a medical laboratory cytotechnologist, a person shall meet one (1) of the following requirements:

(a) Successfully complete two (2) years in an accredited college or university with twelve (12) semester hours in science, eight (8) hours of which are in biology; and

1. Complete twelve (12) months of training in a school of cytotechnology accredited by an accrediting agency approved by the cabinet; or

2. Has received six (6) months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the cabinet and six (6) months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal six (6) months of training.

(b) Has, prior to May 4, 1977:

1. Graduated from high school;

2. Completed six (6) months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytotechnology; and

3. Completed two (2) years of full-time supervised experience in cytotechnology.

(c) Has achieved a satisfactory grade in a proficiency examination approved by the cabinet. After December 31, 1978, initial qualification as a cytotechnologist shall be in accordance with the requirements of paragraphs (a) or (b) of this subsection.

(5) An individual qualifying as a cytotechnologist solely under subsection (4) of this section may supervise technicians and trainees only in the specialty of cytology.

(6) An individual serving as a laboratory technologist or cytotechnologist in Kentucky for a period of one (1) year prior to May 4, 1977, may continue to serve the laboratory in a capacity unless otherwise exempted in subsections (3) and (4) of this section. The cabinet may require, in the interest of the health, safety, and welfare of the people of this state and as a condition to issuance of an original or renewal license, the individual to satisfactorily demonstrate the ability to perform medical laboratory functions under supervision.

Section 4. Medical Laboratory Technicians and Trainees. (1) Medical laboratory technicians shall:

(a) Perform only medical laboratory procedures which require a degree of skill commensurate with their education, training, and technical abilities, and which involve limited exercise of independent judgment.

(b) Perform procedures only in the presence of a qualified medical laboratory technologist, supervisor, or director.

(2) A medical laboratory technician trainee shall perform only repetitive procedures which require a minimal exercise of independent judgment. These procedures shall be performed only under the personal and direct supervision of a qualified supervisor or technologist.

(3) To qualify as a medical laboratory technician, a person shall meet one (1) of the following requirements:

(a) Successfully complete sixty (60) semester hours of academic credit, including chemistry and biology, and a structured curriculum in medical laboratory techniques at an accredited institution, or possess an associate degree based on a course of study including those subjects from an accredited institution.

(b) Be a high school graduate or equivalent and have completed one (1) year in a technician training program in a school accredited by an accrediting agency approved by the cabinet.

(c) Be a high school graduate or equivalent and have two (2) years of pertinent full-time laboratory experience as a technician trainee in a medical laboratory approved by the cabinet.

(d) Be a high school graduate or equivalent, have successfully completed an official military medical laboratory procedures course of fifty (50) weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(e) A person not meeting the training and experience requirements defined in paragraphs (a), (b), (c), or (d) of this subsection may qualify as a medical laboratory technician if the person:

1. Was performing the duties of a medical laboratory technician any time between January 1, 1968, and May 4, 1977; and

2. Had five (5) years of pertinent medical laboratory experience prior to May 4, 1977.

(f) An individual serving as a laboratory technician in Kentucky for a period of one (1) year prior to May 4, 1977, may continue to serve the laboratory unless otherwise exempted in paragraphs (a), (b), (c), (d), and (e) of this subsection. The cabinet may require, in the interest of the health, safety, and welfare of the people of the state and as a condition to the issuance of an original or renewal license, the individual to satisfactorily demonstrate the ability to perform medical laboratory functions under supervision.

(g) Has achieved a satisfactory grade in a proficiency examination approved by the cabinet. After December 31, 1978, initial certification as a technician shall be in accordance with paragraphs (a), (b), (c), or (d) of this subsection.

Section 5. Personnel Policies. Each laboratory shall create and maintain written personnel policies, practices, and procedures that support sound laboratory practice. Work assignments shall be consistent with qualifications. The laboratory shall maintain written employment records which include:

- (1) A resume of each employee's initial and continued training, experience, duties, and date or dates of employment.

- (2) Evidence of adequate health supervision of employees, including results of preemployment physical examinations, including chest X-rays, immunization records, and records of all illnesses and accidents occurring on duty. (3 Ky.R. 198; eff. 5-4-77; Am. 20 Ky.R. 2181; 2637; eff. 3-14-94.)